

Notice of Allowability	Application No.	Applicant(s)	
	10/583,034	GAUTHIER ET AL.	
	Examiner	Art Unit	
	ANNE L. HOLLERAN	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to after-final filed 9/28/2010.
2. ☒ The allowed claim(s) is/are 1-3,5-8 and 16-21.
3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☒ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|---|---|
| <ol style="list-style-type: none"> 1. <input type="checkbox"/> Notice of References Cited (PTO-892) 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) 3. <input type="checkbox"/> Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date _____ 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | <ol style="list-style-type: none"> 5. <input type="checkbox"/> Notice of Informal Patent Application 6. <input checked="" type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date <u>20101006</u>. 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment 8. <input type="checkbox"/> Examiner's Statement of Reasons for Allowance 9. <input type="checkbox"/> Other _____. |
|---|---|

/Alana M. Harris, Ph.D./
Primary Examiner, Art Unit 1643

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EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Bill Schulman on 10/583,034.

The application has been amended as follows:

In the claims:

1. [A] **An isolated** human anti-idiotypic antibody Fab- or scFv-fragment, which mimics Her-2/neu tumor associated antigen, and which comprises CDR1H, **CDR1L, CDR2H, CDR2L, CDR3H and CDR3L, wherein the amino acid sequence of CDR1H consists of the** sequence SYAMS (SEQ ID No: 15), **wherein the amino acid sequence of CDR1L consists of the** sequence QGDSLRSYYAS (SEQ ID No: 16), **wherein the amino acid sequence of CDR2H consists of the** sequence SGGTTYADSVKG (SEQ ID No: 17), **wherein the amino acid sequence of CDR2L consists of the** sequence GKNNRPS (SEQ ID No: 18), and (i) **wherein the amino acid sequence of CDR3H consists of the** sequence SEQ ID No: 3 ~~and~~ **when the amino acid sequence of CDR3L consists of the** sequence SEQ ID No: 4, or (ii) **wherein the amino acid sequence of CDR3H consists of the** sequence SEQ ID No: 5 ~~and~~

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when the amino acid sequence of CDR3L consists of the sequence SEQ ID No: 6, wherein said fragment ~~[is directed against]~~ **binds** trastuzumab F(ab')₂.

2. The fragment of claim 1, **wherein CDR3H consists of SEQ ID No: 3 and CDR3L consists of SEQ ID No: 4** ~~[that comprises a sequence SEQ ID No: 3 in the CDR3 region of the VH domain and a sequence SEQ ID No: 4 in the CDR3 region of the VL domain]~~.

3. The fragment of claim 1, **wherein CDR3H consists of SEQ ID No: 5 and CDR3L consists of SEQ ID No: 6** ~~[that comprises a sequence SEQ ID No: 5 in the CDR3 region of the VH domain and a sequence SEQ ID No: 6 in the CDR3 region of the VL domain]~~.

16. [A] **An isolated** human anti-idiotypic antibody Fab- or ScFv- fragment, which ~~[mimicks]~~ **mimics** Her-2/neu tumor associated antigen, ~~[and which comprises CDR1H of sequence SYAMS (SEQ ID No: 15), CDR1L of sequence QGDSLRSYYAS (SEQ ID No: 16), CDR2H of sequence SGGTTYADSVKG (SEQ ID No: 17), CDR2L of sequence GKNNRPS (SEQ ID No: 18), CDR3H of sequence SEQ ID No: 3 and CDR3L of SEQ ID No: 4, wherein said fragment comprises the amino acid sequence SEQ ID No: 1, this fragment being designated scFv40,~~ **wherein said fragment binds to trastuzumab F(ab')₂**.

19. [A] **An isolated** human anti-idiotypic antibody Fab- or ScFv- fragment, which ~~[mimicks]~~ **mimics** Her-2/neu tumor associated antigen, ~~[and which comprises CDR1H of sequence SYAMS (SEQ ID No: 15), CDR1L of sequence QGDSLRSYYAS (SEQ ID No: 16),~~

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~~CDR2H of sequence SGGTTYADSVKG (SEQ ID No: 17), CDR2L of sequence GKNNRPS (SEQ ID No: 18), CDR3H of sequence SEQ ID No: 5 and CDR3L of SEQ ID No: 6, wherein~~ said fragment comprises the amino acid sequence SEQ ID No: 2, this fragment being designated scFv69, **wherein said fragment binds to trastuzumab F(ab')₂**.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne Holleran, whose telephone number is (571) 272-0833. The examiner can normally be reached on Monday through Friday from 9:30 am to 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Misook Yu, can be reached on (571) 272-0839. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Official Fax number for Group 1600 is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

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system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private

PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll free).

Anne L. Holleran

Patent Examiner

/Alana M. Harris, Ph.D./

Primary Examiner, Art Unit 1643